# Exhibit 53

# Quarterly Compliance Report to the Board of Directors 3Q2013

Bert Weinstein
Vice President, Corporate Compliance
October 28, 2013



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# Compliance Summary for 3Q2013



The Company continues to have good systems and processes in place committed to the prevention and detection of violations, with continuous attention to improvement. There are no significant violations or gaps to report for the 3<sup>rd</sup> quarter of 2013.

### This report highlights:

- The success of efforts to address the highest piority compliance risks through the senior-level Corporate Compliance Council risk assessment process
- Metrics—based Field Sales Compliance results
- Sunshine Act Readiness, including positive Navigant Consulting audit



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# **3Q13 Compliance Risk Reduction**



- Purdue evaluates the highest priority compliance risks through the senior-level Corporate Compliance Council's quarterly meetings
- 31 priority Compliance risks, among eight departments, have been identified and evaluated by the Council (high, medium, low), with quarterly updating of remediation activities
- As of 3Q, the following risk remains rated as "high," but with undertaking to reduce risk level by year-end
  - R&D Publications and Authorship a focus of recent Corporate Integrity Agreements, with very specific compliance requirements; need of updated SOPs



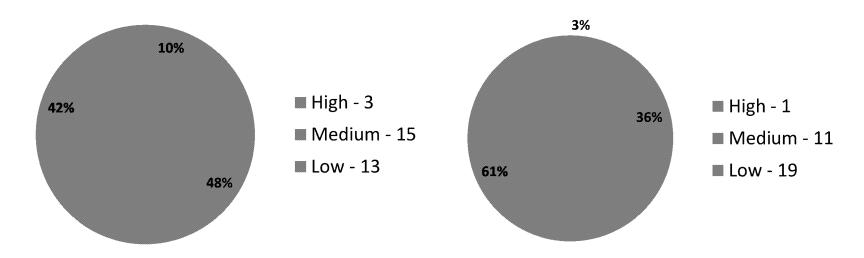
# **3Q13 Compliance Risk Grid**



 With focused activity over the past six months, our 3Q review of priority compliance risks shows actions have reduced overall risk

### **Compliance Risks 1Q13**

### **Compliance Risks 3Q13**





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### **3Q13 Field Sales Call Note Reviews**



Call notes are reviewed for key words and by randomized selection, within 30 days of each month's-end

<b>Total Calls</b>	Reviewed by	% of Calls	Minor, or No	Major	% Reviewed w/
From Field	Compliance	Reviewed	Findings	Findings	Major Findings
246,449	29,180	11.82%	253	10	0.03%

Call note reviews are a cornerstone of our overall sales oversight, with a total of 698 total matters evaluated at weekly Sales Discipline Committee meetings during the 3<sup>rd</sup> quarter

Remediation	# / % Total
DM Coaching	513 / 73%
No follow up needed	81/ 12%
Warning Letter	56 / 8%
Coaching Letter	41 / 5%
<b>Probation Letter</b>	7 / 1%

Top 5 Issues Found	# / % Total
Product Indication Errors	174 / 25%
#Products Discussed vs Reported	103 / 15%
Reformulation Messaging	94 / 13%
Poorly Written Call Note	82/ 12%
Potential Comparative Claim	45 / 6%



# **3Q13 Speaker Program Monitoring**



### Speaker Programs are in government crosshairs

- Each program is monitored with a Field Sales monitoring form
- Independent third party monitors attend ~5% of programs, with selection based on speaker frequency, or for cause
- Most common compliance issues reported: speaker did not stay strictly on label and/or follow the approved slide deck. Remediated through letters to attendees, corrective speaker training, and dismissal of speakers for repeats

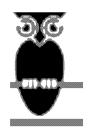
Year	Total Programs	Programs with Compliance Issues	% of Programs with Compliance Issues
2011	968	6	0.62%
2012	1290	12	0.93%
2013	509	3	0.59%



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# **3Q13 Field Contact Reporting**



### Field Contact Reports (FCR) are important

- They are the best means for DMs to monitor and correct sales representative performance in the field, including compliance
- Minimum of 2 days to be reported quarterly by each DM
- Compliance continuously monitors FCR frequency and substance, and provides updates to Sales Management
- For full year 2013:
  - Sales force in aggregate is exceeding the Sales SOP minimum
  - Compliance issues reported by DMs in FCRs are overwhelmingly administrative in nature (late-entered call notes, late expense reporting), and not of a substantive nature



# Sunshine Act is Underway!



- For the period 8/1 12/31/13, spend on HCPs and teaching hospitals to be reported to CMS, on March 31, 2014, for release to public by September 30, 2014; annual reporting thereafter
- What's covered?
  - All payments or transfers of value to physicians and teaching hospitals by pharmaceutical, device, and biologics manufacturers
    - One annual filing will be made for Purdue Pharma LP and its independent associated US Companies deemed to be "Applicable Manufacturers"
    - Foreign affiliates are <u>not</u> considered Applicable Manufacturers due to the fact that their activities are not deemed to constitute "operating in the United States"



# Sunshine Act "Challenges"



### Capturing Clinical Spend

- Obtaining "clean" and accurate data from CROs is industry's greatest challenge; we rely upon their reports of underlying payments to HCPs
- Improvement is expected in the future, and (for such reasons) CMS has advised they do not plan to conduct compliance audits for 2013 data
- Data Disputes: we don't want angry customers!
  - Supporting Documentation should a physician or teaching hospital dispute a spend report, Applicable Manufacturers must be able to demonstrate the accuracy of their reported data
  - Processes are needed for handling disputes and this could involve many stakeholders and intense activity over a short 45-day period
  - Pre-Publication release of data to HCPs is favored to reduce the number of disputes that may be received during the dispute resolution period provided under the statute



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### **How Does Purdue Measure Up?**



- Navigant Consulting Audit engaged by IAF for a two-part audit of the Company systems for Sunshine Act reporting
  - 9/16/13 Systems Audit Report Overall Rating: "Meets Requirements, Minor Issues Noted," with most issues addressed already
  - Transactions Audit Underway awaiting final audit report, with some preliminary findings, mainly around accuracy of supporting documentation (e.g., sign-in sheets, food receipts for in-service HCP meals)
- Interesting to note: For the first half of the year, there were approximately 90,000 total transactions (mostly sales representative in-service meals; CRO transactions not included)





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